

**Testimony of Scott McKibbin
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Testimony Before the House Committee on Oversight and Government Reform

On the Subject of Approval Pathway for Generic Biopharmaceuticals

March 26, 2007

Thank you for the opportunity to speak on behalf of Illinois Governor Rod R. Blagojevich in support of establishing a pathway for generic biopharmaceuticals. I want to applaud Chairman Waxman for his vision in recognizing that the escalating costs of biopharmaceuticals to states and consumers is creating an economic burden on Illinoisans, and state budgets nationwide. These costs will continue to make it more difficult to balance cost control and access for patients to affordable access to life-saving biopharmaceuticals both in Illinois and the nation as a whole. Further, I would like to recognize Illinois Congressman Emanuel for his co-sponsorship of H.R. 1038, the Access to Life-Saving Medicine Act, and for supporting these important measures.

By way of background, I have more than 19 years of experience consulting to large public entities, employers, and foundations on a variety of health care issues.

In my present role as the Special Advocate for Prescription Drugs, I have functional accountability for overseeing the \$2.8 billion dollar annual prescription drug spend for the State of Illinois. My duties include working across agencies and programs to ensure the residents and taxpayers of Illinois are well served. I am also a two-time kidney cancer survivor, and can speak from personal experience on both the value and costs of therapies that treat such dreaded diseases as cancer.

The State of Illinois has a long history of recognizing the need to provide prescription drug assistance to our residents. Illinois was the first state to successfully obtain and implement an 1115 waiver for a SeniorCare Pharmaceutical Program, which expanded prescription drug coverage to seniors and disabled residents, based on income limits. Predating our SeniorCare Program, Illinois maintained a State Pharmaceuticals Assistance Plan (SPAP) for drugs to treat ten (now eleven)-diseases.

Under the leadership of Governor Rod R. Blagojevich, Illinois offers **the most** comprehensive Part D wraparound program (Illinois Cares Rx). And, as of last summer, Illinois offers to EVERY child in Illinois access to health insurance coverage (including prescription drugs) under our AllKids Program.

I want to make it clear that I have a dual role as Special Advocate. The State of Illinois, as in every state, has the responsibility to ensure that the prescription pharmaceuticals

available to consumers are safe and effective. So I would like to dispense with the issue of safety as a given for the discussion of any generic legislation.

From our perspective, creating a process that enables the Food and Drug Administration (FDA) to determine the safety and interchangeability of biopharmaceuticals must be a given. The traditional generic pharmaceutical industry, which was created with the landmark Hatch/Waxman Act of 1984, established a process that tasked FDA with determining how to ensure generic versions of traditional pharmaceuticals could be scientifically determined to be safe, effective and interchangeable with their brand name counterparts.

While some in this debate are seeking to obscure the real issues with inflammatory rhetoric about the potential lack of safety of generic biopharmaceuticals, it is my position that this legislation authorizes FDA to take those scientifically sound steps that are appropriate to ensure the safety of generic biopharmaceuticals.

This is an appropriate role of the FDA, as the agency has the expertise and experience to handle this task. After all, it is the FDA that is charged with overseeing the process for approval of these biopharmaceuticals in the first instance. As a result, I believe that the science is available today to establish a process that will ensure the timely approval of generic versions of biopharmaceuticals. Authorizing FDA to do what it does best, determine which scientific goals are necessary to approve a safe and effective generic, should be beyond the debate of this legislation. I am confident that once the FDA process has been established that the value of generic competition for consumers will become obvious.

The Reality of Biopharmaceutical Costs

I want to focus the bulk of my testimony on the reality of biopharmaceutical costs, and the value of generic competition in this arena. Illinois is a partner with the Federal Government in providing and paying for prescription drugs. We are also responsible for providing and nurturing a sound economy in our state, one that does not allow healthcare costs to bankrupt our state, or one that negatively impacts employers or the overall business climate of our state. To this end, Governor Blagojevich has introduced a comprehensive program to expand or offer coverage to the 1.4 million uninsured between the ages of 19 and 64 and to offer relief to many of our residents who struggle every day to pay for the healthcare cost covered under existing insurance plans.

There should be little debate about the cost of providing prescription medicines. And while there may be some debate about the actual rate of increase of expenditures for biopharmaceuticals, the fact remains that the impact on Illinois of these costly drugs is growing dramatically and will reach a crisis within the foreseeable future.

As I said, there is some debate about whether the annual increase in the cost of biopharmaceuticals is 15%, 17% or 20%. But the difference is in fact not material. If, as I believe and my data shows, that expenditures for these products are rising at an average



of 15% annually, then within five years what Illinois spends on these drugs today will double. That will have a dramatically negative effect. We will not be able to afford these medicines.

Analysis of Illinois Biopharmaceutical Expenditures

Many states probably don't even realize the depth of what they are spending now on biopharmaceuticals. According to IMS, biopharmaceutical sales in 2006 grew to \$40.3 billion. While spending has escalated, a debate over the potential for generic biopharmaceuticals has spanned four FDA commissioners, all with varied levels of prioritization on how to establish a biopharmaceutical generic approval process. States need more than continued discussion on this issue. We need action. Chairman Waxman's bill is a great first step in actually getting us on the road to creating a framework to permit generic competition and the savings it will create.

To understand the breadth of the impact of spending on biopharmaceuticals for Illinois, we examined leading biopharmaceutical products and what the state of Illinois spent on these products. The results were staggering.

For our 227,500-member employee/retiree group, the State of Illinois spent \$33.2 million dollars for a select list of approximately 100 biopharmaceuticals during the fiscal year ending June 30, 2006.

This amount (without trend) represented over 12% of the entire plan cost and is growing at an astronomical rate on both the price and utilization side of the ledger. The ingredient cost increase was 49.9% and the plan cost per member was 50.3%.

The number of prescriptions for this select list of biopharmaceuticals also rose significantly, a nearly 29% increase.

For programs administered under the State Medicaid Agency, will have seen similar cost and utilization increases, but on a much larger scale. For the most recent year in which data is available, the cost of 61 biopharmaceuticals was \$100,662,000 paid under the pharmacy benefit and estimated \$75 million paid for under the medical and Part D wraparound programs. The grand total exceeds \$200 million per year, without trend.

In order to better understand the impact for individual patients, we looked at cost for selected biopharmaceuticals. For example, a patient in our State Employee Group requiring Traceer™, used to treat a condition of high blood pressure in the lungs, cost \$28,300 per patient, per year; a patient requiring Actimmune®, used to treat both children and adults with chronic granulomatous disease (CGD) and osteopetrosis, cost \$38,566 per patient, per year. And finally, a patient prescribed Genotropin®, for long-term treatment of growth failure in different conditions, cost \$17,588 per patient, per year.



Potential for Cost Savings

Now, much has been said about the potential cost savings of generic competition. Opponents to creating a pathway for generic competition argue that the cost savings may only be 10 or 20 percent. Let's look at the worst case savings – 10%. If Illinois were able to reduce the 15% annual increase in spending in biopharmaceuticals by even 10%, then we not only extend our ability to pay for these drugs, but we also extend our ability to continue, under state programs, to provide increased access to them.

And in fact, a 10% or 15% initial savings will equate to real dollars for Illinois. Based on our analysis, \$25 to \$37 million per year (without trend).

Any savings on these expensive drugs will be welcomed. Even a 10% discount on a \$38,000 treatment biopharmaceutical is substantial to our state budget, especially when this savings is compounded over several years. In considering the potential for savings from generic competition, I implore Congress to look not only at their cost today, but also at the impact of savings as a result of the growing usage that has resulted as indications are broadened and as more consumers, who have exhausted other therapeutic options for critical conditions, are prescribed biopharmaceuticals.

The other issue to consider about savings is this. It appears an obvious one from my perspective, but seems lost in the debate. In the past year, biopharmaceutical expenditures have increased at double digit rates. If we do nothing for the rest of 2007, we will end the year with even higher expenditures associated with biopharmaceuticals. Every day that we delay in creating a pathway for generic competition is a day of potential savings lost to states, to taxpayers, to consumers. We cannot afford to wait any longer to begin to save, even if, as opponents predict, that savings will initially only be modest.

Summary: The Time is Now

We must begin on the pathway to creating an approval process for generic biopharmaceuticals today. Every day we delay is a day of potential savings lost, and a day of escalating expenses. And although this may sound dramatic, it is a day closer to Illinois and other states drowning in the red ink of drugs we cannot afford to give to patients that need and deserve them. It is also another day lost for employers, who are seeing an increasing percentage of their healthcare expenses grow as a result of increased usage of biopharmaceuticals.

I urge Congress to approve legislation that will authorize the FDA to apply sound scientific regulatory criteria that will give Illinois, all other states, and every consumer and taxpayer lower cost biopharmaceutical products, and increased access that results from the cost savings.

